

REMARKS

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herewith, which place the application in condition for allowance.

The September 27, 2002 Office Action required an election under 35 U.S.C. § 121 from:

- Group I: Claims 1-25, 88-89, 101-123, 141-142 and 147-151, drawn to a method for repairing and/or generating and/or regenerating myocardium and/or myocardial cells comprising the administration of somatic stem cells; a method of implanting or depositing cells or causing the implantation or depositing of somatic stem cells in cardiac or blood vessel tissue comprising administration of somatic stem cells; a pharmaceutical composition comprising a therapeutically effective amount of somatic stem cells; and, a kit and a method for making the same pharmaceutical composition, classified in class 424, subclass 93.1;
- Group II: Claims 26-52 and 124-140, drawn to a method of repairing and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of a cytokine; a method of implanting or depositing cells or causing the implantation or depositing of somatic stem cells in cardiac or blood vessel tissue comprising administration of a cytokine, classified in class 424, subclass 85.1;
- Group III: Claims 53-87, 99-100, 143-144 and 147-152, drawn to a method of repairing and/or generating and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of somatic stem cells and a cytokine, a pharmaceutical composition comprising a therapeutically effective amount of somatic cell and a selected cytokine; and, a kit and a method for making the same pharmaceutical composition classified in class 424, 93.1, 85.1;
- Group IV: Claims 145-146, drawn to a pharmaceutical composition for use in the treatment, therapy or prevention of cardiovascular disease or related complaint and a pharmaceutical composition for use in repairing and/or generating and/or regenerating recently damaged myocardium and/or myocardial cells, which cannot be classified because the chemical structure of the composition is not recited; and

Group V: Claim 153, drawn to a method of treating damaged myocardium and/or myocardial cells comprising the recited steps, classified in class 435, subclass 1.1.

The Office Action additionally requires an election of species as follows:

If Group I is elected, election must also be made from between:

- a. myocytes;
- b. smooth muscle cells; and
- c. endothelial cells.

If Group II is elected, election must also be made from between:

- a. stem cell factor;
- b. granulocyte-colony stimulating factor;
- c. stromal cell-derived factor-1;
- d. interleukin-3;
- e. granulocyte-macrophage colony stimulating factor;
- f. macrophage colony stimulating factor;
- g. steel factor; and
- h. vascular endothelial growth factor.

Additionally, if Group II is elected, a further election must also be made from between:

- a. myocytes;
- b. smooth muscle cells; and
- c. endothelial cells.

If Group III is elected, a election must be made from between:

- a. stem cell factor;
- b. granulocyte-colony stimulating factor;
- c. stromal cell-derived factor-1;
- d. interleukin-3;
- e. granulocyte-macrophage colony stimulating factor;
- f. macrophage colony stimulating factor;
- g. steel factor; and
- h. vascular endothelial growth factor.

Additionally, if Group III is elected, a further election must also be made from between:

- a. myocytes;
- b. smooth muscle cells; and
- c. endothelial cells.

Applicants elect, with traverse, for further prosecution in this application, the invention of Group II, drawn to a method of repairing and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of a cytokine; a method of implanting or depositing cells or causing the implantation or depositing of

somatic stem cells in cardiac or blood vessel tissue comprising administration of a cytokine, classified in class 424, subclass 85.1. Applicants further elect stem cell factor and myocytes for examination. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The present invention relates to methods for repairing and/or generating and/or regenerating myocardium and/or myocardial cells and pharmaceutical compositions for use in such methods. The present claims, therefore, represent a web of knowledge and continuity of effort that merit examination in a single application. Indeed, the claims in Groups I, II and III are all classified in class 424.

In this regard, the Examiner's attention is respectfully requested to review MPEP § 808.02 which states, "even with patently distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

1. Separate classification;
2. Separate status in the art; or
3. Different field of search[.]”

Contrary to the guideline mandated by the MPEP, the claims of all ten Groups involve methods for repairing and/or generating and/or regenerating myocardium and or myocardial cells. Thus, restriction is not appropriate. More specifically, contrary to the guideline mandated by the MPEP, the claims of at least three of the five Groups are related since the claims are classified in the same class. Thus, restriction is not appropriate.

Additionally, the Examiner's attention is further respectfully invited to review the text of MPEP § 803 which in part states:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Thus, the mere allegation that the Groups identified in the Office Action are distinct ignores the interrelationship of the methods of repairing and/or generating and/or regenerating

myocardium and/or myocardial cells. Therefore, examination of any of these five groups mandates consideration of the patentable elements in all of them.

There is no showing in the Office Action that there would be any undue or serious burden in examining Groups I through V in this application. Accordingly, it is respectfully submitted that the Office Action is fatally defective and the restriction requirement cannot stand.

Turning now to the species election, the Examiner is respectfully requested to review M.P.E.P. §808.01(a), which states that “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required (July 1998). In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants’ claims are directed to, *inter alia*, a method of repairing and/or generating and/or regenerating myocardium and/or myocardial cells. The species election requires the selection of a single cytokine and a single cell type for examination. It is respectfully submitted that the search and examination would be sufficiently co-extensive such that the cytokines and cell types should be searched and examined as a whole. Unity of invention, therefore, exists, such that the requirement for species elections should be withdrawn.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between the claims of all five Groups. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the above, reconsideration and withdrawal of the Requirements for Restriction and Election of Species are requested.

CONCLUSION

In view of the remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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